DEC 5 2005

MEDIVEN BUTLER 510(K) SUMMARY

I. General Information on Submitter

Name: medi USA L.P.
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Whitsett, NC 27377
Telephone: (336) 449-4440
Fax: (336) 449-4495
Name of Contact Person: Scarlette Foust
Date Summary Prepared: October 7, 2005

II. General Information on Device

Trade Name: medi Butler

Classification Name: Application Aid, Accessory to a Medical Support Stocking

III. Predicate Devices

21 C.F.R. § 880.5780(a)

IV. Description of the Device

The Butler is a lightweight steel frame application aid that solves the often difficult problem of applying compression stockings. The application aid is suitable for all compression stocking sizes.

V. Intended Use

The medi Butler is indicated for use as an accessory to medical support stockings to prevent pooling of blood in the legs. The medi Butler aids in the application of medical support stockings to the legs.

VI. Technological Characteristics of Device Compared to Predicate Device

The medi Butler consists of similar construction to other devices that have been used as accessories to medical support stockings. As per the FDA's request, because the Agency does not have a current 510(k) application on file for this class of accessory device, we have provided comparison information for the Jobst Stocking Donner, a Class I 510(k) exempt accessory to medical support stocking for general medical purposes, using welded steel alloy construction that has been painted. The medi Butler's steel alloy composition is designed to enhance the strength of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 5 2005

Medi USA, L.P.
C/O Mr. Gary L. Yingling
Kirkpatrick & Lockhart Nicholson Graham LLP
1800 Massachusetts Avenue, N.W.
Washington, DC 20036

Re: K051324
Trade/Device Name: Med: Butler
Regulation Number: 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: November 4, 2005
Received: November 9, 2005

Dear Mr. Yingling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K051324

Indications for Use

510(k) Number: K051324

Device Name: medi Butler

Indications for Use: Prescription

The medi Bulter is indicated for use as an accessory to medical support stockings. The medi Butler is a lightweight steel frame aid for the application of medical support stockings to the legs. The medi Butler is suitable for all compression stocking sizes.

Prescription Use **Yes**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use **NO**
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

For ADW 11/2/c

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) K051324